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Supreme Court, U.S.
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No. 03-1237

IN THE
Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE and TELIOS PHARMACEUTICALS, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION OF INTEGRA LIFESCIENCES I, LTD. AND THE BURNHAM INSTITUTE

RAPHAEL V. LUPO
Counsel of Record
NATALIA V. BLINKOVA
MCDERMOTT WILL & EMERY LLP
600 13th Street, N.W.
Washington, D.C. 20005
(202) 756-8000

Attorneys for Respondents Integra Lifesciences I, Ltd. and The Burnham Institute

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QUESTION PRESENTED

"[T]o facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent" (App. 12a), Congress enacted 35 U.S.C. § 271(e)(1), the so-called "FDA exemption." The statutory provision exempts from patent infringement a narrow class of activities "solely for uses reasonably related to the development and submission of information" to the FDA. "In this case, the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds." (App. 12a). Did the Federal Circuit err in holding that Section 271(e)(1) "simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process" (App. 13a) and thus does not extend to "the Scripps-Merck general biomedical experimentation" (App. 14a)?

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STATUTORY PROVISION

35 U.S.C. § 271(e)(1):

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

INTRODUCTION

The question presented by the Federal Circuit's decision in this case does not pertain to — as Merck presents it — a "drug-research safe harbor." (Merck Petition for Writ of Certiorari, "Petition," at i). While Congress could have easily used Section 271(e)(1) to enact a research safe harbor, it did not. Instead, Congress worded the statute to exempt only activities "solely for uses reasonably related to the development and submission of information under a Federal law...". Accordingly, the actual question presented pertains to whether Section 271(e)(1)'s "FDA safe harbor" extends not only to compiling information actually requested by the FDA, but also to basic research aimed to identify new drug candidates that may someday — however distant — be submitted to the FDA for approval.

The Federal Circuit did recently curtail the common law research exception under the patent laws. It did so, however,

in a different case. *See Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002). Not only did Merck not raise the common law research exception as grounds for its appeal; it explicitly disavowed that exception at oral argument.

Similarly, the Federal Circuit did not — as Merck intimates — limit Section 271(e)(1) to generic drugs. (Petition at 3-4, 15-17). The Federal Circuit plainly acknowledged that the scope of the FDA exemption is "not limited to generic drug approval." (App. 36a). The panel simply recognized that the statute — bound by the words "solely for uses reasonably related" — presents a factual issue to the jury and cannot be stretched so far as to "reach any exploratory research that may rationally form only a predicate for future FDA clinical tests." (App. 13a). Thus, the *Integra* panel held that sufficient evidence supported the jury's factual determination that the infringing activities in question were too remote to qualify as "reasonably related" to the FDA drug approval process. While Merck makes much of Judge Newman's dissent, she agreed with the majority on this point. (App. 33a, "I agree that 'the §271(e)(1) safe harbor [does not] reach back down the chain of experimentation to embrace development and identification of new drugs.'"). Judge Newman based her dissent upon the common law research exemption, an issue Merck failed to raise with either the Federal Circuit or this Court. (App. 24a; App. 6a n.2).

It is Merck, not the Federal Circuit, that proposes a rule of law divorced from the statutory language. Merck's proposed exemption for all research relating to any drug possibly subject to FDA approval ignores the statutory language and legislative history of Section 271(e)(1). Worse yet, applying such a *per se* rule would deprive all biomedical "tool patents" useful to the drug research process of legal protection — hardly the *de minimis* effect on patent rights intended by Congress. As the panel cautioned, "expansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents." (App. 13a-14a).

This case is not about curing cancer or other deadly diseases. This case is about money. It is about whether pharmaceutical companies can avoid sharing some small part of the billions upon billions of dollars they make with innovators who devise research tools that enable them to discover and develop new drugs. It is about a pharmaceutical company attempting to sidestep the *quid pro quo* upon which this country's patent system has been based since the ratification of the Constitution.

STATEMENT OF THE CASE

Drs. Erkki Ruoslahti and Michael Pierschbacher, scientists at The Burnham Institute, made a series of pioneering discoveries in the early 1980's concerning the importance of the amino acid sequence "RGD" and corresponding cell surface receptors to cell adhesion proteins. These compounds govern the mechanisms by which cells attach and detach from certain proteins of the extracellular matrix. (A5436-A5446; A5449-52; A5927).[1] The patents at issue in this lawsuit cover these pioneering inventions and are exclusively licensed to Integra LifeSciences I, Ltd. ("Integra").

In the early 1990's, Dr. David Cheresh ("Cheresh") of The Scripps Research Institute ("Scripps") learned that the cell surface receptors patented by Integra take part in angiogenesis, the process by which tumors in the body obtain blood supply that allows them to grow. (A7150-58). Cheresh used RGD peptides supplied by Merck KGaA ("Merck") to block the receptor, thereby inhibiting angiogenesis and arresting the growth of new blood vessels that "feed" tumors. (A10086-93). All of the Merck-supplied

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[1] Citations to "A____" reference the Joint Appendix filed below.

RGD peptides — EMD 66203, EMD 85189, and EMD 121974 — were covered by claims in Integra's patents. (A24-25; A5949-56).

In 1995, Merck and Scripps entered into an agreement designed to develop an angiogenesis-inhibiting drug using Integra's RGD technology. To help identify the best drug candidates, Merck paid Scripps and Dr. Cheresh over 6 million dollars to screen potential compounds using the patented RGD peptides as controls. (A10106-107; A15114-15). Scripps and Cheresh were obligated to screen up to 100 Merck compounds per year using Merck-supplied RGD peptides. Merck anticipated carrying out the actual FDA-related work itself once Scripps identified the best compound for the commercial pipeline. (A10106-08). In fact, Scripps' laboratories were not Good Laboratory Practices certified, as is required for certain FDA data. (App. 48a; A34; A6968-69; A7287).

Upon learning of the Merck-Scripps agreement, Integra immediately approached Merck with an offer to license the patents-in-suit. (A5519-34). Merck rejected all of Integra's licensing efforts and on July 18, 1996, Integra filed a patent infringement action against Merck, Scripps, and Dr. Cheresh in the Southern District of California. Integra alleged, *inter alia*, that Merck induced infringement by Scripps and Cheresh by supplying the infringing RGD peptide compounds and by contracting for their infringing use in screening drug candidates and general biomedical experiments. Merck and Scripps asserted that the experiments at issue were exempt from infringement under either the common law research exception or the so-called FDA exemption, 35 U.S.C. § 271(e)(1). (A505-506). Under Merck's theory, any research to identify or develop a drug that would be subject to FDA approval prior to being marketed for human use would be exempt from the patent laws.

Prior to submitting the case to the jury, the district court found all pre-1995 experiments exempt under the common law research exception (A8618-19), and submitted the remaining experiments to the jury to resolve the factual dispute whether the "reasonable relationship" test was met under the FDA exemption. Applying the *Intermedics* test, the jury found that Merck's activities were not sufficiently related to obtaining FDA approval to fall within Section 271(e)(1). The jury found that Merck willfully infringed and induced infringement of each of the patents in suit, based upon evidence that Merck paid Scripps to use Integra's patented invention as a "tool" to screen possible drug candidates. The jury awarded Integra $15,000,000 in damages for Merck's infringing activities. (App. 4a). The district court without prejudice denied Integra's request for prospective injunctive relief (App. 44a), and entered judgment against Merck on September 29, 2000 (A5-6).

The Court of Appeals for the Federal Circuit ("Federal Circuit") agreed with the district court's interpretation of the FDA exemption, 35 U.S.C. § 271(e)(1), and affirmed the jury's verdict of infringement. In construing the statutory provision, the Federal Circuit recognized that "the scope of the safe harbor is not limited to generic drug approval" (36a, citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990)), and that "this court has permitted clinical trials and demonstrations of medical devices under § 271(e)(1)." (App. 10a, citing *Intermedics, Inc. v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993)).

Here, the panel faced a different question, "whether the § 271(e)(1) safe harbor reaches back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval." (App. 10a). Finding that "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new

pharmaceutical compounds," the panel held that "[e]xtending § 271(e)(1) to embrace all aspects of new drug development activities would ignore its language and context with respect to the 1984 Act in an attempt to exonerate infringing uses only potentially related to information for FDA approval." (App. 13a). Such an expansive reading would, in turn, "vitiate the exclusive rights of patentees owning biotechnology tool patents." (App. 13a-14a).

The panel's reading of the statute, far from "non-textual and unprecedented," as Merck claims (Petition at 2), thus preserves the delicate balance between reducing delays in the FDA approval process with only a *de minimis* effect on existing patent rights. Indeed, Scripps continues its research activities using the infringing peptides, just as Merck continues to provide infringing peptides to other scientists in the U.S., who continue to use the compounds in biomedical research and continue to publish their results.[2]

REASONS FOR DENYING THE WRIT

I. THE QUESTION PRESENTED TURNS ON FACT, NOT LAW.

As posed by the Petitioner, the Question Presented asks whether the Federal Circuit erred in concluding that the FDA exemption "does not protect animal studies of the sort that are essential to the development of new drugs ...". (Petition at i). But the jury made no findings, and, indeed the panel

[2] *See, e.g.*, Rex A. Moats *et al., Micro-MRI at 11.7T of a Murine Brain Tumor Model Using Delayed Contrast Enhancement,* 2 Molecular Imaging 150, 158 (2003)(thanking Merck scientists for providing the active αv-integrin antagonist EMD 121974 used in experiments discussed in the article). EMD 121974 was one of the RGD peptides found by the jury to Infringe Integra's patents.

made no pronouncements, about "animal studies of the sort that are essential to the development of new drugs." Applying the same *Intermedics* standard espoused by Merck in its submissions pre- and post-trial (A506; A759), the jury simply found the experiments in question too removed from the FDA approval process to qualify for the statutory exemption. As the district court noted in upholding the jury's verdict, defendants' own witnesses testified at trial that neither Merck's nor Scripps' infringing activity was necessary to carry out any preclinical work for submission to the FDA. (App. 49a). The district court explained that,

> The jury is entitled to make credibility decisions, and the evidence provides sufficient grounds for the jury to disregard as not credible Dr. Cheresh's testimony that the infringing experiments performed at Scripps were done for FDA purposes. Considered as a whole, the evidence is sufficient to establish that Merck, and not Dr. Cheresh or any other Scripps scientist, was responsible for conducting FDA related experiments, and that any connection between the infringing Scripps experiments and FDA review was insufficiently direct to qualify for the exem[ption].
>
> Considering the jury's right to weigh the evidence and determine the credibility of the witnesses, the evidence, when viewed in the light most favorable to plaintiffs, was sufficient for the jury to have returned a verdict in plaintiffs' favor.

(App. 49a-50a).

Thus, while the Petition attempts to frame the Question Presented as one of law, it is actually one of fact.

II. THE FEDERAL CIRCUIT OPINION IS CONSISTENT WITH THE LANGUAGE OF THE STATUTE, ITS LEGISLATIVE HISTORY, AND PRECEDENT.

A. THE FEDERAL CIRCUIT OPINION DOES NOT LIMIT SECTION 271(e)(1) TO GENERIC DRUGS.

The Petition boldly asserts that under the panel's interpretation of Section 271(e)(1), the safe harbor protects only manufacturers of generic, not new drugs. According to Merck, "the practical consequence of the Federal Circuit's distinction is that the safe harbor protects only copy-cats, not innovators." (Petition at 4). Yet the panel opinion makes explicit that "the scope of the safe harbor is not limited to generic drug approval." (App. 36a, citing *Eli Lilly*, 496 U.S. 661). In fact, the Federal Circuit issued an errata to the *Integra* opinion, designed to clarify any doubts as to the application Section 271(e)(1) to pioneer drugs. (*See* App. 36a-37a). Merck's distinction — in view of the express language of the opinion — is a false dichotomy.

On appeal, Merck sought to convert the "FDA exemption" into a general research exemption even though the jury applied the *Intermedics* standard proposed by Merck in both its pre- and post-trial submissions. (A506; A759). Merck argued to the Federal Circuit that Section 271(e)(1) must be interpreted to exempt from infringement all "rational predicates" to FDA submission — any research activity in the chain of causation that could ultimately lead to the development of information relevant to FDA approval. Indeed, Merck was forced to embrace this all-encompassing "rational predicate" standard to overcome the substantial evidence supporting the jury's determination that the Merck-Scripps infringing activities were not "reasonably related" to obtaining FDA approval.

The issue before the court of appeals was thus "whether the section 271(e)(1) safe harbor reaches back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval." (App. 10a). The panel concluded that the infringing activity — screening dozens of compounds in a general search for possible drug candidates — comprised "only general biomedical research to identify new pharmaceutical compounds," adding that "[t]he FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval." (App. 12a). Thus the jury could reasonably find that the Scripps-Merck experiments lacked the necessary nexus to FDA submission to qualify as "reasonably related" to FDA clinical tests. "Section 271(e)(1)," the panel explained, "simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process. The safe harbor does not reach any exploratory research that may rationally form only a predicate for future FDA clinical tests." (App. 13a). Stated differently, "[t]he safe harbor does not reach any exploratory research that may form a predicate for future FDA clinical tests." (*Id.*).

Far from being "unprecedented," the opinion below closely follows previous interpretations of Section

271(e)(1).[3] Indeed, the *Integra* opinion relies on this Court's holding in *Eli Lilly* to reiterate that Section 271(e)(1) is not limited to approval of generic drugs, a point Merck conveniently ignores in its attempt to manufacture an issue for certiorari. As Integra argued in opposing Merck's petition for rehearing *en banc* before the Federal Circuit, if the appellate opinion limited the application of Section 271(e)(1) to generic drugs, it would have necessarily rejected the *Intermedics* standard, which exempts from infringement both pioneering and generic drug experiments "reasonably related (relatively directly)" to regulatory approval. 775 F. Supp. at 1280. Rather than depart from *Intermedics,* as Merck contends, the panel applied its proximate relationship test to Merck's pioneering drug research, just as the jury did under the jury instruction agreed upon by the parties.

B. THE PLAIN LANGUAGE OF SECTION 271(e)(1) EXEMPTS ONLY ACTIVITIES "REASONABLY RELATED" TO FDA APPROVAL.

Section 271(e)(1) exempts otherwise infringing uses "reasonably related to the development and submission of information under a Federal law which regulates the manu-

[3] The Federal Circuit has not previously addressed the issue of how far back the FDA exemption reaches in the chain of experimental causation. Prior decisions of the Federal Circuit cited in the Petition, such as *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997) or *Intermedics, Inc. v. Ventritex Co.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993), addressed the issues of dual use, wherein information that was clearly for FDA purposes was also used for non-FDA purposes. The Federal Circuit considered whether using FDA generated information for non-FDA purposes renders the FDA exemption unavailable. These cases did not decide what level of general biomedical research occurring prior to commencing FDA clinical studies could qualify as "reasonably related" to the FDA approval process.

facture, use, or sale of drugs ..." 35 U.S.C. § 271(e)(1). The statutory words "reasonably related" are key. Congress' choice of the word "reasonably" requires a proximate, rather than an attenuated, relationship between the infringing experiments and the FDA approval process. While "the term 'reasonably' permits some activities that are not themselves the experiments that produce FDA information to qualify as 'solely for uses reasonably related' to clinical tests for the FDA," the statutory language "limits the reach of that relationship test." (App. 11a). Accordingly, the phrase "reasonably related" has been interpreted to mean that the activity in question "to contribute (relatively directly) to the generation of the kinds of information likely to be relevant" to the FDA approval process. *Intermedics,* 775 F. Supp. at 1280.

On appeal, Merck argued that the statutory phrase "reasonably related" must "encompass all drug development research that serves as a rational predicate to generating information for submission to the FDA, including any tests conducted to determine whether to proceed with a drug candidate." (Brief for Defendant-Appellant Merck KGaA at 45). Merck's "rational predicate" standard deviates dramatically from the "reasonably related" language chosen by Congress (and included in the jury instruction), and shifts the inquiry away from the proximity between FDA review and the infringing activity. Merck's "ends justify the means" approach impermissibly expands the scope of the statute and renders the plain language "reasonably related" superfluous.

Section 271(e)(1) was not designed to exempt general biomedical research from infringement. As the Petition concedes, *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.* 733 F.2d. 858 (Fed. Cir. 1994) provided much of the impetus for the FDA exemption. (Petition at 3). In *Roche*, the Federal Circuit upheld a finding of infringement where the only infringing acts were those of a generic drug manufac-

turer engaged in bioequivalency studies for purposes of securing FDA marketing approval. Congress' legislative response to the *Roche* decision was thus limited to creating a statutory exemption tied specifically to satisfying FDA requirements. Had Congress intended to frame the exemption more broadly, it could have easily written the statute to exempt all "research" or "rational predicates" to the development of any drug regulated under Federal law. Congress instead chose to preserve the rights of tool patent holders and to enact the "reasonably related" standard that pertains to information objectively and reasonably related to the FDA approval process.

C. THE LEGISLATIVE HISTORY CONFIRMS THAT SECTION 271(E)(1) WAS ENACTED FOR THE LIMITED PURPOSE OF CORRECTING THE *DE FACTO* EXTENSION OF PATENT TERMS CAUSED BY DELAYS INHERENT IN THE FDA APPROVAL PROCESS.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("DPC-PTR Act") to remedy two unintended distortions of the seventeen-year patent term: (1) the delay in reaping the commercial benefit of patented products due to the need for FDA approval prior to marketing and (2) the unwarranted extension of the patent term on a pioneering drug's sales to consumers due to the inability of competitors to begin testing for FDA approval of a generic version of that drug until after the patent term has expired. *See Eli Lilly*, 496 U.S. at 669-670; *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524 (Fed. Cir. 1992).

Section 271(e)(1) was designed to remedy this second distortion. *Eli Lilly*, 496 U.S. at 671. Because of the lengthy FDA review procedure required for generic drugs, a competitor's generic could not be sold until a number of years after the patent on the pioneering drug expired, thus effectively extending the patent monopoly on drugs beyond the statutory time period. The Section 271(e)(1) exemption furthered Congress' "objective of getting safe and effective generic [drug] substitutes on the market as quickly as possible after the expiration of the patent." H.R. Rep. No. 98-857(II), at 9 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693. Without this limited exception, "generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent" on a pioneering drug. *Id.*, at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692.

As the Federal Circuit recognized, although the words of the statute do not confine the exemption to generic manufacturers, the legislative history does manifest Congress' intent to limit the scope of the exemption to achieve a reasonable balance between the rights of patent holders and drug manufacturers: "the *only activity* which will be permitted by the [DPC-PTR Act] is a limited amount of testing so that generic manufacturers can establish the bioequivalence of a generic substitute" for a pioneering drug already on the market. *Id.* (emphasis supplied). Similarly, the House Report states that the "information which can be developed under this provision is the type which is required to obtain approval of the drug." *See* H.R. Rep. No. 98-857(I), at 45 (1984), *reprinted in* 1984 U.S.C.C.C.A.N. 2647, 2678. Based on this limitation, Congress concluded the "nature of the interference with the rights of the patent holder is not substantial." H.R. Rep. No. 98-857(II), at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692.

The "rational predicate" interpretation offered by Merck to the Federal Circuit improperly expands the exemption, and if adopted would seriously impede the ability of biotechnology companies who develop research tools to protect their patent rights. *See discussion in* David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 Hous.

J. Int'l L. 615, 661-43 (1994) (Unduly broad application of § 271(e)(1) exemption could make certain biotechnology patents virtually incapable of ever being infringed). The House Report makes it clear that the exemption was meant to have an insubstantial effect on patent rights. H.R. Rep. No. 98-857(II), at 8, 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2692, 2714 ("the nature of the interference is *de minimus* [sic]"). Similarly, the House Report states that the "information which can be developed under this provision is the type which is required to obtain approval of the drug." *See* H.R. Rep. No. 98-857(I), at 45 (1984), *reprinted in* 1984 U.S.C.C.C.A.N. at 2678.

By using the word "reasonably," Congress intended Section 271(e) to balance the need for the exemption against the need to preserve patent rights. Granting the Petition would upset that balance and eliminate an entire field of patent rights, all to permit large drug companies to avoid paying licensing fees for their use of biotechnology tools for drug research. As the Federal Circuit warned, "expansion of § 271(e)(1) to include Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents." (App. 13a-14a).

III. THE PETITION MISSTATES THE EFFECT OF THE *INTEGRA* DECISION ON BIOMEDICAL RESEARCH.

The Petition theatrically casts the panel decision as a radical departure from precedent, doomed to halt biomedical research and transform the United States into a "hostile territory for drug innovation." (Petition at 4). Nonsense. Merck simply seeks to change the law to accommodate its facts.

Most of the experiments at issue involved using the infringing compounds in a chicken egg membrane experimental model. Tests results from such chicken egg experiments, as Merck's scientists agreed, have no correlation to human disease. (A8358; A4932; A34-35). The "animal" models exalted by the Petition — while useful to general biomedical research — are unsuitable for FDA purposes.

No record evidence even suggests that the decision below has or will inhibit drug research and development. In fact, Scripps scientists admitted that even after being sued for infringement, they continued to conduct infringing experiments. Indeed, the majority of the infringing experiments occurred *after* Scripps was sued. To this day, over four years after trial, Merck continues to provide infringing peptides to scientists engaged in cancer research throughout the United States. Even the article relied upon in the Petition, Dan Reiser, *Pre-Clinical Research Bombshell,* 23 Pharms. Executive 38 (Dec. 1, 2003) explains the likely result of the case is not cessation of research, but rather the licensing of necessary technologies by drug companies so as to justifiably reward patent owners. Drug research has not stopped. Patient health is not at risk. Only the size of Merck's purse is at stake.

CONCLUSION

The true goal of this Petition is called out in the brief of the *amici*: the pharmaceutical industry wants a substitute for the ever-shrinking common law research exemption, previously relied upon by drug companies in appropriating the technology of others. *See* Petition of *Amicus Curiae* The Association of the Bar of the City of New York for Rehearing *En Banc* at 5-7. The only means for achieving this result is redrafting the statute, a task that belongs to Congress.

Merck's petition for a writ of certiorari should be denied.

Respectfully submitted,

RAPHAEL V. LUPO
Counsel of Record
NATALIA V. BLINKOVA
MCDERMOTT WILL & EMERY LLP
600 13TH STREET, N.W.
WASHINGTON, D.C. 20005
(202) 756-8000

Attorneys for Respondents
Integra Lifesciences I, Ltd.
and The Burnham Institute